INSTRUCTIONS FOR COMPLETING THE MEDICAL DEVICE REPORTING SEMIANNUAL USER FACILITY REPORT, FORM FDA 3419

Under 21 CFR Part 803.33, the MDR regulation requires that user facilities submit a semi-annual summary report to FDA of all reportable adverse events submitted to manufacturers or the FDA during a designated reporting period. A semi-annual report would not be required if there were no reportable events submitted during the applicable reporting period. The semi-annual report must provide the following information:

- Semi-annual reports must be submitted by January 1 for reportable events that were filed from July through December and by July 1 for reportable events that were filed from January through June.

PART 1

1. **REPORT PERIOD:** Check the applicable box and provide the 4-digit calendar year in which the adverse event reports were filed.

2. **USER FACILITY ID (HCFA OR FDA PROVIDED NUMBER):** Provide the user facility HCFA or FDA provided number, which consists of the user facility's 10-digit Health Care Financing Administration (HCFA) number used for medical device reports or the number assigned by the FDA for reporting purposes in accordance with 21 CFR Part 803.3(dd).

3. **USER FACILITY INFORMATION:** In items 3a-f, provide the user facility's name and complete address.

4. **USER FACILITY CONTACT INFORMATION:** In items 4a-g provide the name, complete address and telephone number of the individual designated as the facility's contact person responsible for reporting to FDA.

5. **TOTAL NUMBER OF REPORTS ATTACHED OR SUMMARIZED:** List the total number of reportable events that are attached or summarized .

> 5a-b: Enter the lowest and the highest user facility report number submitted during the reporting period. The report numbers consist of the HCFA or FDA provided number, the 4-digit calendar year in which the reports were submitted and the 4-digit sequence number assigned to the adverse event.

For each adverse event report listed in the range of numbers identified in items 5a and 5b, attach a photocopy of the completed MedWatch FDA Form 3500A or alternatively, you may complete Part 2 of this form for each identified event.

6. **SIGNATURE OF CONTACT:** Provide the signature of the contact person listed in item 4a.

7. **DATE OF REPORT:** Enter the date that this report form is completed.

PART 2

- This section must be filled out for each reported adverse event if not covered in an attached photocopy of the 3500A.

1. **USER FACILITY EVENT REPORT NUMBER:** Enter the user facility HCFA or FDA provided number, the 4-digit calendar year in which the adverse event was reported and the 4-digit sequence number assigned to that individual adverse event.

2. **WHERE WAS REPORT SUBMITTED?:** Check all the boxes that would apply.

3. **MANUFACTURER INFORMATION:** In items 3a-f, provide the name and complete address of the manufacturer. If the manufacturer is unknown, enter "UNK" in item 3a. and skip to item 4.

4. **DEVICE INFORMATION:** Enter the applicable device information in items 4a-f, listing the brand name, common name, model, serial, lot and/or catalog number. Enter "NA" for any item that does not apply or enter "UNK" for any item that is not known.

5. **BRIEF DESCRIPTION OF EVENT:** Provide a brief narrative of the reported adverse event.